Interview

Jeffrey Bacha speaks to Zardia Swift on the upcoming
2nd World Orphan Drug Summit,
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Jeffrey Bacha
Chief Executive Officer
Del Mar Pharmaceuticals

Jeffrey Bacha is the President & CEO of Del Mar Pharmaceuticals, a company which he co-founded in 2010 to rapidly develop and commercialize proven cancer therapies in new indications where patients are failing modern targeted or biologic treatments. Mr. Bacha is a seasoned executive leader with nearly twenty years of life sciences experience in the areas of operations, strategy and finance. His background includes successful public and private company building from both a start-up and turn around perspective; establishing and leading thriving management and technical teams; and raising capital in both the public and private markets. Mr. Bacha serves as a Director of Sernova Corp. (TSX-V: SVA), was the founding CEO of Inimex Pharmaceuticals Inc and co-founder of XBiotech and Urigen Holdings Inc. He has also held positions as and Exec. VP Corporate Affairs & Chief Operating Officer at Clera Inc., VP Corporate Development at Inflazyme Pharmaceuticals Ltd. (TSE: IZP) and Senior Manager & Director at KPMG Health Ventures. Mr. Bacha has been recognized as a "Top 40 under 40" executive by Business in Vancouver magazine and is the former Chair of the Greater Vancouver Economic Council. Mr. Bacha is active in his community through volunteerism with the Leukemia & Lymphoma Society's Team in Training program and as Chairman of the Board for Covenant House Vancouver, an organization dedicated to assisting at-risk and homeless youth to re-enter society. He received his MBA(honors) from the Goizueta Business School at Emory University and a B.Sc. (BioPhysics/Premed) from the University of California, San Diego.

Could you tell me about your background and what led to your interest in orphan drug development?

My background in general is in science and finance. I think what led us specifically into orphan drug development in cancer were a couple of things. Firstly, in our industry there is a goal and desire to do something positive to impact patient outcomes. At the same time, the financial returns that support an orphan drug opportunity can be very meaningful. We are driven to impacting patient outcomes in as streamlined and efficient manner as possible.

How did Del Mar Pharmaceuticals come about as a company and what are your goals and objectives for the future?

Del Mar Pharma is a company formed around a lead drug, VAL-083, which my co-founder Dr. Dennis Brown had been incubating for some time. This is a drug where previous clinical studies sponsored by the National Cancer Institutes in the United States some years ago suggested activity against a number of different cancers, but for a number of reasons VAL-083 was never commercialized.

What we've done, in a similar fashion to what Salmedix did with Treanda™ and what Dr. Brown

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also did at ChemGenex with Omapro™, is to take a look at the mechanism of the drug and where it may have a place in the modern treatment of cancer. In this case the opportunity was in the treatment of glioblastoma multiforme, or "GBM" for short, the most common and aggressive form of brain cancer, where roughly half of those diagnosed will fail both front-line therapy and, in the United States the second-line therapy, Avastin. We believe the mechanism of VAL-083 has a lot of opportunity in GBM and so we're essentially trying to modernize the drug in an indication where data from twenty years ago already suggests clinical activity. That scientific driver got us excited about the product. The team around VAL-083 is a group that is operating on a virtual basis and who have all worked together in some fashion in the past. So everybody has at least one degree of overlap in his or her professional history. The team driving this project also has a history of over twenty successful oncology products.

We believe that VAL-083 has great promise to deliver patient benefit in the GBM patient population.

What would you say are the key changes for drug developers in the development and commercialization of orphan drug products?

The obvious initial challenge is financial: If an orphan indication is relatively small, the financial community may need to be educated in terms of the opportunity for a return before they are willing to support product development. We are relatively lucky in that other companies before us have gone into the GBM space and therefore the investment community appreciates the financial opportunity. Then the other challenge is in regulatory affairs: Designing a clinical study that will be able to access the patient population in the order to generate the data required for approval. If you've got an indication that has only several thousand patients a year and a study that requires several hundred patients for approval, it becomes a challenge in terms of demonstrating safety and activity in a timely manner. We believe we have a viable strategy to manage this challenge as well.

In your experience, how do the FDA alter their clinical study's criteria for ultra orphan diseases vs orphan diseases?

I think that the FDA is very good at trying to enable companies to develop products to address these orphan indications. One particular thing that they do is in the case of the ultra-orphan indication where there is no comparable therapy, is the ability to achieve an approvable endpoint based on surrogates. It may also be possible to gain approval based on a single-armed trial design in an ultra-orphan indication where there is no current therapy. This is clearly something that the agency has adapted from its traditional metrics to respond to the specific needs of the orphan drug field.

What do you think can be done to get patient organizations and industry working together more collaboratively to improve patient access to orphan drugs?

I think awareness of new available therapies not only to patients, who tend to be quite aware of

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what the treatment opportunities are, but also making sure that the medical community is well aware of new therapies that are available to treat rare conditions. And finally, making sure that the reimbursement community is aware of the value of new treatment paradigms. Cancer has been particularly unique in terms of its reimbursement and the willingness of the payers, both in the United States and elsewhere, to reward the developer with a competitive rate of return on development. In many cases, non-cancer orphan indications are still not paid for in a way that is going to motivate research and development.

I think it could be said that the political forces behind and the public perception driving investment in cancer research are different to some other diseases. That has been somewhat driven by the public perception and fear that is cancer is ultimately lethal. The opportunity to extend someone's life, even if it's just for a few months, is so meaningful in many different ways that it has achieved the favorable attention of the reimbursement community. This is different to other diseases, in that they may not create such a powerful emotional driver which I believe has benefitted the reimbursement paradigm for cancer.

What are you hoping to come away with from the World Orphan Drug Summit, and looking at the agenda are there any specific discussions you're hoping to have?

It's a fantastic agenda and the focus on orphan diseases is somewhat unique. The fact that the meeting is now in its second year shows that there is an interest broadly in treating these smaller indications. From Del Mar Pharma's perspective we look forward to hearing presentations and discussions from the larger players who have a sales and marketing force that are reaching out to these patients. We are essentially a development company, with a clinical stage product. Understanding how companies with a larger infrastructure view development-stage products is important to us. By gaining a better understanding of what those companies are hoping to see before moving into a collaborative arrangement or even acquisition we will be able to focus our efforts. It's a great opportunity to have everyone from the discoverers, to the financiers, to companies with sales and marketing infrastructures in the room together. Having that full continuum is definitely something that we're looking forward to being a part of.

Jeffrey will be presenting at the 2nd World Orphan Drug Summit taking place Boston, MA, 15th – 17th November 2011.